PROSKAUER ROSE LLP
Richard M. Goldstein (RG 8329)
Michael T. Mervis (MM 0306)
Lawrence I. Weinstein (LW 0792)
Baldassare Vinti (BV 0080)
Victoria L. Loughery (VL 0172)
Eleven Times Square
New York, NY 10036
Tel: 212.969.3000
Fax: 212.969.2900

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CHURCH & DWIGHT CO., INC.,

Plaintiff,

v.

SPD SWISS PRECISION DIAGNOSTICS, GMBH,

Defendant.

Civil Action No. 14 CV 585 (AJN)

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

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PRELIMINARY STATEMENT

C&D's Complaint alleges the following facts which, on this motion, are presumed true: (1) the Weeks Estimator cannot estimate how long a woman has been pregnant; (2) SPD falsely advertises that the Weeks Estimator can tell a woman how long she has been pregnant; and (3) SPD's false advertising is material to consumers and injured C&D, SPD's prime competitor.[1]

Even after repeated reading of SPD's motion to dismiss brief ("MTD Br."), SPD's rationale as to why the Complaint fails to state a claim for relief remains elusive. As a unanimous Supreme Court reiterated just last month in a Lanham Act false advertising case, a federal court's obligation to hear and decide cases within its jurisdiction "is virtually unflagging." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. _, slip op at 6 (2014) ("*Lexmark*"), *quoting Sprint Communications, Inc. v. Jacobs*, 571 U.S. _, slip op at 6 (2013). To understand when, *if ever,* a federal court can decline to hear a Lanham Act suit about an FDA-regulated product where, as here, the plaintiff has standing to sue, requires a careful analysis of (i) the differing purposes of the Lanham Act and the federal Food, Drug & Cosmetic Act (the "FDCA"); (ii) the facts and rationale of the cases that have dismissed Lanham Act suits in deference to FDA decision-making; (iii) the relevance of those cases to the facts C&D alleges here; and (iv) the impact of *Lexmark* and the impending decision in *Pom Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170 (9th Cir. 2012), *cert. granted*, 134 S. Ct. 895 (2014).

SPD's brief contains none of this analysis. Instead, the motion to dismiss is dependent on a fundamental mischaracterization of C&D's Lanham Act claim. In addition, SPD improperly asks this Court to consider on this motion, through a Request for Judicial Notice ("RJN"), private email communications between SPD and FDA that C&D's Complaint neither mentioned nor

[1] Church & Dwight ("C&D") uses in this Memorandum the same defined terms as in its opening preliminary injunction brief (Dkt. No. 19).

relied on. Then, confusingly, SPD urges the Court to ignore those communications and dismiss the Complaint anyway (*see* MTD Br. 9 n.2). Finally, SPD relies on cases bearing no relation in fact or law to this one, and from them, conjures up the vague (and non-existent) principle that dismissal is required to avoid "undermin[ing] the FDA's exclusive authority." *Id*. at 10.

It simply is **not** the law that FDA's regulation of pregnancy test kits ("ptks"), through the 510(k) clearance process, requires or even permits this Court to dismiss C&D's Lanham Act claim. The hypocrisy of SPD's present position is starkly illustrated by the fact that in the parties' prior Lanham Act litigations, SPD took the *opposite* position. There, SPD asserted that "the 510(k) [clearance] process . . . **entails no FDA approval of either the efficacy of [C&D's ptk products] or the veracity of its advertising claims**."[2] Thus, said SPD then, the court should find that two C&D ptks are ineffective at detecting pregnancy as early as 5 and 6 days before a woman's missed period, **despite FDA's express clearance of those products** to be marketed as effective at detecting pregnancy **at those precise time points**.[3]

It is crystal clear from a close examination of the case law, including the cases SPD cites, that **none** of the circumstances that have caused courts in the past to decline to consider a competitor's Lanham Act claim about an FDA-regulated product are presented here. Those circumstances were where: (a) the suit was merely a disguised attempt to enforce the FDCA, because the plaintiff did not allege any facts other than a purported FDCA violation to support its claim of false advertising; (b) resolution of the suit would have required the court to interpret ambiguous statutory language in the FDCA or in an FDA regulation that FDA had not yet construed; (c) the suit's allegations of false advertising implicated FDA regulations that the

[2] All emphasis in quotations is supplied unless otherwise indicated.
[3] *See SPD Swiss Precision Diagnostics, GmbH v. Church & Dwight Co., Inc.,* Case No. 09-0291-BZ (N.D. Cal. 2009), Dkt. 7 at 2, and *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH,* 3:10-cv-00276-FLW-TJB (D.N.J. 2010), Dkt. 5 at 2**.**

agency was then re-considering; or (d) the alleged false statement was expressly permitted by FDA regulations or by an FDA-cleared statement of intended use.[4]

First, contrary to SPD's mischaracterizations, the Complaint is not a back door attempt to enforce an FDCA violation. The Complaint's gravamen is that (i) SPD's Weeks Estimator commercial (the "Commercial"), (ii) the label language on the outside of the Weeks Estimator box SPD marketed from the Product's launch last August through the date of the Complaint (and beyond), and (iii) other Weeks Estimator digital and retail advertising, all falsely communicate the message that the Weeks Estimator can tell women how long they have been pregnant. As the Complaint specifically alleges, that message is false. Indeed, physicians uniformly measure the duration of a woman's pregnancy based on the date of her last menstrual period ("LMP"), not on the number of weeks since she last ovulated, and there is a material difference between how many weeks have passed since ovulation, and how many weeks, according to her doctor, she has been pregnant. Thus, if a woman relied on SPD's false advertisements, she would believe she was significantly less far along than her doctor would tell her, raising the potential for serious health consequences.

That is the reason SPD's challenged advertising is not only false, but dangerous. Indeed, SPD itself admits the Weeks Estimator cannot measure pregnancy duration, albeit in a tiny disclaimer buried on the side of the package, and in the Product's insert, which consumers **cannot** see until after purchase, by which time it is too late for Lanham Act purposes to dispel their confusion, and prevent C&D from losing sales.

[4] In the parties' previous litigation, C&D argued that SPD was precluded from challenging the efficacy of C&D's ptks at certain time points before a woman's missed period because the FDA had expressly cleared those products as safe and effective for their intended use of detecting pregnancy at those very time points. Here, C&D is not challenging the Weeks Estimator's efficacy for the intended uses that FDA permitted SPD to claim, namely to detect that a woman is pregnant and to estimate weeks since ovulation. Instead, C&D challenges the Weeks Estimator's ability to do what FDA said the Product **cannot do**, namely to estimate the **duration** of pregnancy**.**

Second, SPD's assertion that adjudicating C&D's claims would require a reversal of the FDA's clearance of the Weeks Estimator (*see* MTD Br. 1-2) is flat out false. The FDA clearance letter (the "Clearance Letter") (Compl. Ex. A), unequivocally reflects FDA's **agreement** with C&D's position that the Weeks Estimator **is not capable** of measuring pregnancy duration, and FDA's refusal to let SPD market the Product for that purpose (although SPD did so anyway). It is entirely proper for the Complaint to allege this, because FDA scientific findings consistent with a Lanham Act plaintiff's allegations are strong evidence of falsity under the case law.[5]

Finally, it is important to note the fundamental fallacy permeating SPD's motion, namely that FDA "approved" SPD's false advertising. First, SPD's purported "evidence" of this – its RJN Exhibits – consists of SPD's private correspondence with FDA that C&D had no notice of or access to. Under the Second Circuit's controlling decision in *Chambers v. Time Warner, Inc.*, 282 F.3d 147 (2d Cir. 2002), these documents cannot be considered on SPD's Rule 12(b)(6) motion, because C&D did not rely on (or even know about) them when drafting the Complaint.

Moreover, even if the Court were to consider the RJN documents, they do not support SPD's motion. FDA's communications with SPD show that FDA believed the SPD advertising identified in the Complaint, including the package label SPD used from the Product's launch through the filing of the Complaint and beyond, as well as the Commercial and SPD's other non-label advertising, all violated the intended use limitations of the Clearance Letter, which barred SPD from claiming the Product estimates the duration of pregnancy (*see* RJN Exs. H-I). FDA's communications with SPD also show that FDA believed the Weeks Estimator package label (including the revised label SPD recently began shipping) is *not* adequate, *standing alone*, to

[5] The other circumstances in which courts have dismissed Lanham Act claims concerning FDA-regulated products all involved situations where either the meaning of ambiguous FDA regulations was a matter of first impression or FDA regulations presently were being re-evaluated by that agency. This case does not turn on the interpretation of any FDA regulations, whether ambiguous, subject to agency re-evaluation, or otherwise.

protect against confusion about the Product's intended use. Thus, FDA also required SPD to make certain disclosures in the package insert (RJN Exs. B, D-G), which consumers can read before they use the product but not until **after** they buy it.

None of this permits dismissal of the Complaint. FDA's position on the SPD advertising discussed in the Complaint is entirely consistent with C&D's allegations that those advertisements are false. And, FDA's comments about SPD's *new* label language serve only to highlight the important differences between the FDCA and the Lanham Act. The FDCA tasks FDA with protecting public safety by ensuring that over-the-counter ("OTC") medical devices sold to consumers are safe and effective for their intended use. The FDA's limited regulation of ptk labels is not for the purpose of assisting competitors, but rather to assess whether the proposed language on the product box, **coupled with the proposed insert consumers can read only after purchase**, collectively inform the consumer, before she **uses** the product, of its proper intended use. Moreover, FDA's regulation of ptks does not require any pre-clearance review of commercials or other advertising, and SPD alleges no such review in its motion to dismiss.

In contrast, the Lanham Act's prohibition of false advertising is designed to protect the advertiser's *competitors and other persons* "who allege an injury to a *commercial* interest in reputation or sales." *Lexmark*, slip op. at 13. The time when a Lanham Act plaintiff such as C&D is most likely to be harmed by its competitor's false advertising is at or before the time of sale, when untruthful advertising statements can influence a consumer to purchase the false advertiser's product instead of the plaintiff's. Thus, the FDA may be satisfied that a product's label, coupled with the package insert -- if read -- adequately explains the limitations on intended use before a purchaser uses the product. But for a competitor of the false advertiser, package inserts are equivalent to closing the barn door after the horse has left, because the inserts are not

read (if at all) until after the consumer has been deceived into buying the product. Therefore, to deter unfair competition, the Lanham Act – unlike the FDCA – provides a private right of action to plaintiffs like C&D who suffer a commercial injury due to another party's false advertising.

Nor do any of the cases SPD cites permit dismissal here. The Supreme Court has long directed courts to give full effect to competing federal statutes when Congress does not dictate otherwise, which it did not do in enacting either the Lanham Act or the FDCA. And last month, in *Lexmark*, the Supreme Court expressly cautioned courts about dismissing suits on prudential grounds, holding, in direct reference to the Lanham Act, that a court "cannot limit a cause of action that Congress has created merely because 'prudence' dictates." Slip op. at 9. Because there is no irreconcilable conflict in this case between the Lanham Act's interest in redressing a competitor's injury caused by defendant's pre-purchase false advertising, and FDA's interest in protecting consumer safety prior to product use, SPD's motion must be denied.[6]

THE COMPLAINT'S ALLEGATIONS

SPD began marketing the Weeks Estimator in or about August 2013. Compl. ¶2. Like C&D's ptk devices, the Weeks Estimator is designed to tell a woman if she is pregnant. *Id.* ¶17. According to the Clearance Letter (*id*. Ex. A), the Weeks Estimator also can estimate a range of weeks that has passed since a woman ovulated. *Id.* The FDA does not permit a new ptk to be marketed for a particular intended use without a clearance letter *for that use* under 21 CFR § 807.92(a)(5). Compl. ¶20. The Weeks Estimator Clearance Letter makes plain that FDA does not want women to think they can use the Product to estimate how long they have been pregnant. *Id.* ¶22. Thus, the Clearance Letter directs SPD that "Weeks Estimator Results should not be expressed as 'weeks pregnant' and should only be explained as the number of weeks that may

[6] Moreover, as we discuss in the Argument section of this brief, *Lexmark* may foreshadow the Supreme Court's reversal of the Ninth Circuit's decision in *POM*, which would even further limit any restrictions on the ability of a Lanham Act court to adjudicate the merits of false advertising suits concerning FDA-regulated products.

have passed since ovulation." *Id.* Ex. A, at 2. Ovulation is a biological event; it is the point at which a woman's egg is released from one of her ovaries. Compl. ¶18.

Particularly meaningful is the FDA's direction (which SPD disregarded) that the statement of "indications for use" be "*prominently"* displayed on promotional materials for the Weeks Estimator. *Id.* ¶23 (emphasis in original). That statement provides in relevant part (*id*. ¶24, emphasis in original), that the Product:

> *cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that cannot be substituted for a doctor's determination of gestational age. Only a doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression.*

SPD's False Advertising of the Weeks Estimator

Upon launching the Weeks Estimator last summer, SPD began an aggressive false advertising campaign. Compl. ¶2. SPD's false advertising appeared in various media, including the label on the Weeks Estimator box, the widely-aired Commercial, internet advertising, and point-of-purchase advertisements. *Id.* ¶25. SPD's advertisements all conveyed the unambiguous message that the Product can tell a woman how many weeks she has been pregnant. *Id.* ¶42. The Complaint alleges that this message is false; the Weeks Estimator can only estimate the number of weeks since a woman last ovulated, and if a woman used weeks since ovulation instead of date of LMP to estimate how long she has been pregnant, her estimate would be materially different than the doctor's estimate, and potentially expose her to serious health risks. *Id.* ¶¶18, 42-43. The Complaint also alleges SPD's admission on the Product label (in tiny type), that the Product cannot estimate pregnancy duration (*id*. ¶42), as well as FDA's scientific determination that the Weeks Estimator is incapable of measuring pregnancy duration. *Id.* ¶43.

Due to SPD's false advertising, the Weeks Estimator immediately reached sales levels virtually unprecedented for a new ptk. *Id*. ¶46. That is not surprising because, as SPD's website noted, there would be considerable consumer interest in a product that can estimate how long a woman has been pregnant (*id.*), which SPD falsely tells consumers the Product does.

ARGUMENT

When deciding a motion to dismiss, a court must treat the Complaint's factual allegations as true and draw all reasonable inferences in plaintiff's favor. *Harris v. Mills*, 572 F.3d 66, 71 (2d Cir. 2009). Dismissal under Rule 12(b)(6) is warranted only if a complaint does not contain "enough facts to state a claim for relief that is plausible on its face." *Mayor & City Council of Baltimore v. Citigroup, Inc.,* 709 F.3d 129, 135 (2d Cir. 2013). Obviously, a Court's analysis of plausibility is based on what the Complaint alleges, not on the moving party's re-framing of that pleading. Thus, SPD's mischaracterizations of the Complaint must be disregarded. *See, e.g., Mateo v. Bristow,* 2013 U.S. Dist. LEXIS 106478, at *16-17 (S.D.N.Y. July 16, 2013); *Buntin v. City of New York*, 2005 WL 66888, at *3 (S.D.N.Y. Jan. 11, 2005).

I. THE COMPLAINT STATES A PLAUSIBLE AND COGNIZABLE CLAIM FOR RELIEF UNDER THE LANHAM ACT

SPD does not contend that the Complaint fails to meet the above pleading standards. In fact, the Complaint alleges each of the necessary elements of a false advertising claim (*see* ¶¶64-70), supported by extensive factual averments.[7] *See id*. ¶¶3, 18, 26-43, 46, 49 and 68-69.

II. SPD'S REQUEST FOR JUDICIAL NOTICE SHOULD BE DENIED

SPD confusingly requests judicial notice of numerous documents submitted in support of its MTD and then, virtually in the same breath, asks this Court to decide the MTD "without

[7] To establish a Lanham Act false advertising claim, a plaintiff must allege that (1) the defendant has made a false or misleading statement; (2) that has actually deceived or is likely to deceive a substantial portion of the intended audience; (3) the deception is material (*i.e*., likely to influence purchasing decisions); (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been injured as a result of defendant's misrepresentation. *See* 15 U.S.C. §1125; *S.C. Johnson & Son, Inc. v. Clorox Co*., 241 F.3d 232, 238 (2d Cir. 2001).

referencing any facts beyond the complaint and clearance letter." MTD Br. 9 n.2. In fact, under controlling Second Circuit authority, this Court must deny SPD's RJN.

"Generally, when a defendant attempts to counter a plaintiff's complaint with its own factual allegations and exhibits, such allegations and exhibits are inappropriate for consideration by the court at the motion to dismiss stage." *Reyes v. County of Suffolk*, 2014 U.S. Dist. LEXIS 14934, at *5 (E.D.N.Y. Feb. 6, 2014). An exception to that general rule is that a Court may consider documents "asserted within the four corners of the complaint, the documents attached to the complaint as exhibits, and any documents incorporated in the complaint by reference." *James v. Correct Care Solutions,* 2013 U.S. Dist. LEXIS 151710, at *6 (S.D.N.Y. Oct. 21, 2013) (citing *McCarthy v. Dun & Bradstreet Corp*., 482 F.3d 184, 191 (2d Cir. 2007)).

Here, the Complaint neither relies on nor incorporates by reference any of the documents appended to the RJN. Indeed, as to RJN Exs. B and D-I, it would have been impossible for C&D to do so, because those documents are private emails between SPD and FDA to which C&D had no access until SPD disclosed them in connection with its motion to dismiss. In *Chambers,* 282 F.3d at 153, the Second Circuit held that "a plaintiff's reliance on the terms and effect of a document in drafting the complaint **is a necessary prerequisite** to the court's consideration of the document on a dismissal motion." Thus, under *Chambers*, RJN Exhibits B and D-I cannot be considered.

A. In Any Event, The RJN Documents Do Not Support SPD's Argument

SPD wants the Court to take 'notice' of RJN Exhibits B, D, E, F and G because, according to SPD, they show that FDA allegedly reviewed a Weeks Estimator label before clearing the product to be marketed. But, besides being an improper subject of judicial notice, this supposed fact is irrelevant because **SPD admits it never sold the Weeks Estimator in a package containing the label language it submitted to the FDA prior to clearance**. *See*

MTD Br. 7-8. Instead, SPD concedes that before it began selling the Weeks Estimator, it switched to a different package than the one FDA reviewed. *Id.* When FDA eventually learned of SPD's switch, it objected. *Id*.

While RJN Exhibits H and I address some of the advertising at issue in the Complaint, they do nothing for SPD's argument. Exhibit H is a November 2013 post-clearance email to SPD from an FDA scientific reviewer, stating that it had come to FDA's attention that SPD was marketing the Weeks Estimator in violation of the limitations in the FDA clearance letter. Exhibit I is a November 2013 SPD email reply to the same FDA reviewer, attaching SPD's draft minutes of an FDA meeting, as well as a proposed SPD "mitigation plan," including proposed revised labeling and a proposed revised commercial. Far from showing that FDA blessed the package label SPD had been using since the Product launched, or the Commercial and other SPD advertising discussed in the Complaint, Exhibits H and I demonstrate the exact opposite. And, as to the revised label, FDA made no statement that it would, in the absence of the package insert, be truthful and non-misleading.

III. C&D'S LANHAM ACT CLAIM IS NOT PRECLUDED BY THE FDCA

The frequent repetition of a falsehood does not make it more credible, and that is so with SPD's misstatements that the Complaint seeks to enforce the FDCA and to challenge FDA's clearance of the Weeks Estimator. *See, e.g.*, MTD Br. 14. In fact, the Complaint does neither. [8]

A. The Complaint Does Not Seek To Privately Enforce The FDCA

To convince the Court that C&D is suing SPD for violations of the FDCA, SPD cites to snippets from the Complaint that reference FDA or its actions. *See* MTD Br. 14-15. However,

[8] SPD's sole argument for dismissal of C&D's N.Y. GBL § 349 claim is that it rises and falls with C&D's Lanham Act claim. MTD Br. 19. Because, for the reasons set forth herein, C&D has pleaded a viable Lanham Act claim, C&D's NY GBL claim survives as well. *See Johnson & Johnson Vision Care, Inc. v. CIBA Vision Corp*., 348 F. Supp. 2d 165, 178 n.6 (S.D.N.Y. 2004).

when the Complaint is read in full, it is obvious C&D is claiming a violation of the Lanham Act, not asserting a claim for violation of the FDCA. The Complaint does not allege that SPD's advertising is false solely because FDA did not clear the Weeks Estimator for the intended use of determining pregnancy duration. Rather, the Complaint alleges that SPD's advertising **is false because (i) the Weeks Estimator cannot measure pregnancy duration**; instead, it measures the length of time since ovulation, which is different than the length of time since her LMP (the method doctors uniformly use to determine pregnancy duration), and (ii) if a woman used SPD's product to estimate pregnancy duration, she would get a very different result than what her doctor would tell her, which could lead to serious health issues. Compl. ¶¶3, 18, 41-43.

To be sure, the Complaint pleads facts showing that FDA *agrees* with C&D's position that the Weeks Estimator cannot measure the duration of pregnancy, and that FDA did not clear the Product to be marketed for that intended use. Pleading those facts is appropriate in a Lanham Act complaint, and is not an attempt to privately enforce the FDCA. *See Loreto v. P&G*, 515 F. App'x 576, 580 (6th Cir. 2013) (holding plaintiff's false advertising claim not an attempt at private enforcement of the FDCA where, "[e]ven though the FDA has apparently concluded that Vitamin C has not been proven effective in cold treatment, plaintiffs' claim does not depend upon this determination and would logically exist even in its absence"). The fact that FDA's scientific conclusion **is consistent with C&D's position** constitutes additional factual support for C&D's claim of false advertising in violation of the Lanham Act. *See, e.g., Zeneca Inc. v. Eli Lilly & Co.,* 1999 U.S. Dist. LEXIS 10852, at *97-98 (S.D.N.Y. July 15, 1999) (Lanham Act case holding that while "FDA's views are not determinative . . . [n]evertheless, it is appropriate to consider the views of the FDA on the highly regulated issue of drug efficacy"); *Bracco Diagnostics, Inc. v. Amersham Health, Inc.,* 627 F. Supp. 2d 384, 469 (D.N.J. 2009) (Lanham

Act case stating that "courts have consistently held that the FDA's scientific findings are not only relevant, but entitled to significant deference").

B. FDA Clearance of the Weeks Estimator Does Not Immunize SPD From A Lanham Act Claim

In arguing that if this Court decides in C&D's favor, it would "undermine the FDA's exclusive authority," SPD relies heavily on the Ninth Circuit's *POM Wonderful* decision, 679 F.3d 1170 (9th Cir. 2012), *cert. granted* 134 S. Ct. 895 (2014). But while SPD's brief includes "cert. granted" in its citation of *POM* (MTD Br. 10), SPD utterly ignores the significance of that fact.

The FDA regulates juice beverages and ptks. However, unlike this case, what was at issue in *POM* was FDA's promulgation of a comprehensive set of juice labeling regulations that were uniformly applicable to all juice manufacturers, and that only took effect after an extensive notice and public comment period during which the entire juice beverage industry had the opportunity to be heard. *See* Brief of the Coca Cola Company in Opposition to Petition, at 2-3.[9]

POM, a maker of pomegranate juice beverages, brought a Lanham Act false advertising suit against Coca-Cola, alleging that the name of the latter's fruit juice, called "Pomegranate Blueberry Flavored Blend of 5 Juices," and the way that name was presented on the juice label, deceived consumers into believing that pomegranate was a primary ingredient, when in fact the beverage contained less than 0.5% pomegranate juice by volume. The Ninth Circuit affirmed the grant of summary judgment barring POM's Lanham Act claim about the Coca-Cola product's name on the ground that that name was expressly permitted by the FDA regulations, and also dismissed POM's Lanham Act claim against other aspects of defendant's juice label.

[9] For convenience, a copy of Coca-Cola's brief is attached as Exhibit A to the Declaration of Victoria L. Loughery ("Loughery Decl.").

It is no wonder that SPD's brief ignores the facts of *POM*, because even if the Ninth Circuit's decision is upheld, *POM* provides no support for SPD's motion. In *POM*, plaintiff's claim that the name of defendant's juice product constituted false advertising **directly conflicted** with the FDA's comprehensive, uniform juice label regulations, which explicitly permit the product name defendant chose. Here, by contrast, C&D's claim that SPD's advertising is false because the Weeks Estimator cannot tell women how long they have been pregnant **is consistent with** FDA's scientific finding. And, as for FDA's purported post-clearance review of SPD's new label (RJN Ex. I), it was both informal and private – as fundamentally different as can be imagined from the public, industry-wide rulemaking process in *POM*. *See Iams Co. v. Nutro Prods., Inc.,* 2004 U.S. Dist. LEXIS 31136, at *15 (S.D. Ohio July 17, 2004) (rejecting argument that court should "defer" to FDA determination embodied in an informal FDA letter).

Moreover, the Supreme Court's grant of certiorari, and the language of its unanimous *Lexmark* decision, cast serious doubt on the viability of the Ninth Circuit's decision. The Supreme Court granted certiorari despite the opposition (for different reasons) of both Coca-Cola and the United States. The Government took the position that because the FDA had promulgated a regulation establishing comprehensive, industry-wide regulations for juice labeling that clearly permitted the name Coca-Cola chose for its beverage, dismissal of POM's false advertising claim about that name was proper. But more importantly for this case, the Government agreed with plaintiff/petitioner that the Ninth Circuit fundamentally erred in holding that the comprehensive nature of FDA regulation of juice drinks precluded plaintiff's Lanham Act claim challenging other aspects of defendant's juice label.

In arguing that Lanham Act challenges to juice labeling are not precluded by the fact that FDA extensively regulates that labeling, the Government asserted, just as C&D does here, that

the FDA does not administer the Lanham Act, and has no authority to resolve a competitor's claim of business injury due to a misleading label. Brief of the United States in Opposition to Petition for Writ of Certiorari ("U.S. Cert. Br."), at 15 (citing *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005)) (FDA has no procedure to resolve a competitor's false advertising claims because it lacks authority to award compensatory or punitive damages); Brief of the United States in Support of Neither Party ("U.S. Merits Br."), at 27.[10] In addition, the Government noted that the fact that FDA does not accept formal petitions by competitors to take enforcement action against false advertising cuts against permitting FDA regulation of a product to deprive competitors of their right to sue under the Lanham Act for false advertising. U.S. Br. 14; U.S. Merits Br. 27.[11] In short, as the United States explained, "FDA's expertise . . . is not deployed in a way that justifies categorically depriving petitioner of a cause of action under Section 43(a) of the Lanham Act." U.S. Br. 15.[12]

The Government is also plainly correct in asserting that the FDCA and Lanham Act serve different, though largely complementary, purposes, and that there is no evidence in the text or legislative history of either statute that Congress intended the FDCA to preclude Lanham Act suits by a competitor claiming commercial injury caused by false advertising of a product closely regulated by FDA. U.S. Merits Br. 30. In the medical arena, the FDCA is "directed to protecting the public by ensuring that drugs [and medical devices] sold in the marketplace are 'safe, effective, and not misbranded.'" *See Mut. Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 933 (C.D. Cal. 2006) (citation omitted). To the limited extent the FDCA regulates

[10] Copies of the U.S. Cert. Brief and the U.S. Merits Brief are attached as Exhibits B and C (respectively) to the Loughery Decl.

[11] SPD cited C&D's supposed right to petition the FDA as a reason for depriving C&D of its right to sue SPD for its false Weeks Estimator advertising. MTD Br. 10.

[12] Despite its disagreement with this aspect of the Ninth Circuit's ruling, the United States opposed cert because it did not believe there was a true circuit conflict. U.S. Br. 19-21. As the above citations to the Government's brief on the merits reflect, the Government has reasserted its positions in its appeal brief and has urged the Supreme Court to reverse this aspect of the Ninth Circuit decision.

advertising of medical devices and related products, it does so "**not** to protect consumers from deceptive advertising, but rather to further the FDCA's underlying goal of ensuring the safety of" the regulated products. *In re Epogen & Aranesp Off-Label Mktg. and Sales Practices Litig.*, 2009 WL 1703285, at *7 n. 4 (C.D. Cal. June 17, 2009). There is no private right of action for violations of the FDCA or FDA regulations, including the provisions prohibiting misbranding. *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.,* 902 F.2d 222, 230 (3d Cir. 1990). In contrast, the Lanham Act was enacted to "protect persons engaged in commerce against unfair competition" (*see generally* 15 U.S.C. § 1127), and does so by (among other things) providing a private remedy to parties that suffer a commercial injury because of another party's false advertising. *Lexmark*, slip op at 12.

Thus, rather than conflicting, the Lanham Act and FDCA work together to protect against confusion in the marketplace that could result in physical harm to consumers and commercial injury to the advertiser's competitors and other businesses. U.S. Merits Br. 12-13. Given the distinct purposes of the two statutes, it simply makes no sense that a competitor is precluded from obtaining recourse under the Lanham Act for lost sales caused by the advertiser's false statements, merely because the subject of the advertisement is a product that FDA closely regulates. SPD's position makes even less sense on the facts here, where (i) there was no pre-clearance review of any of the SPD advertising discussed in the Complaint, (ii) FDA subsequently found SPD's advertising to be in violation of the Agency's clearance limitation, and (iii) unlike in *POM*, C&D's Lanham Act claims do not conflict with, or require interpretation of, any FDA regulations. *See Pediamed Pharms., Inc. v. Breckenridge Pharm., Inc*., 419 F. Supp. 2d 715, 723 (D. Md. 2006) ("the FDA's administrative scheme should not be

allowed to 'eviscerate a Lanham Act or related common law claim over which the agency has no jurisdiction.'") (quotation omitted).

In situations such as this, where it is obvious the two statutes are "capable of coexistence," it is "the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143-44 (2001). Neither the FDCA nor the Lanham Act contains any indication that the former trumps the latter when alleged false advertising concerns FDA-regulated products. *Mut. Pharm. Co.,* 459 F. Supp. 2d at 934. Therefore this Court must regard the Lanham Act, not the FDA, as supplying the remedy for the injury C&D suffered due to SPD's false statements.

Even without considering the Supreme Court's looming *POM* decision, or its just-decided *Lexmark* decision, a review of SPD's other cases readily reveals their inapplicability to this lawsuit. Those cases concern Lanham Act claims that, unlike the Complaint here, either: (1) were based solely on a purported FDCA violation, with no independent reasons alleged why the statement in question was false or misleading; (2) required the court to preemptively interpret or apply ambiguous FDCA or FDA regulations; or (3) would require the court to countermand FDA's clearance of a product as safe and effective for its intended use.

For instance, in *PhotoMedex, Inc. v. Irwin,* 601 F.3d 919 (9th Cir. 2010), on which SPD heavily relies, plaintiff claimed that defendant falsely advertised its new laser device as being FDA-cleared because, according to plaintiff, the new version had been so significantly modified from the previous FDA-cleared version that defendant was obligated to obtain a new FDA 510(k) clearance, which defendant had not done. The Court found that it could not determine whether, in fact, the defendant's new product required FDA clearance because FDA has the

exclusive authority to determine whether a new 510(k) clearance is required. *Id*. at 928. *PhotoMedex* obviously is distinguishable from the facts here, because C&D does not allege that SPD's advertising was false because SPD did not obtain FDA clearance for the intended use of telling a woman how many weeks she has been pregnant. Rather, the Complaint alleges that SPD's advertising is false because, for the reasons explained at pp. 6-7, *supra,* the Product **is not capable of** telling a woman how long she has been pregnant. *See* Compl. ¶18, 42. The fact that the Complaint alleges that FDA's own scientific findings comport with C&D's position that SPD has engaged in false advertising is not remotely akin to alleging that SPD's advertising is false solely because SPD violated the FDCA by not obtaining a clearance to market its product for the intended use of detecting pregnancy duration. Thus, the holding in *PhotoMedex* does not support dismissal of C&D's Lanham Act claims.

Nor does *Sandoz, supra,* support SPD's motion. There, the Court declined to consider plaintiff's Lanham Act claim on the ground that to adjudicate that claim, the Court would have to determine whether the FDA would classify a particular ingredient as "active" or "inactive" under the FDCA, which the FDA had not yet done. 902 F.2d at 230-32. Here, SPD does not allege the existence of any ambiguous FDA regulation or language in the FDCA requiring this Court's original interpretation. And there is none.

Am. Home Prods. Corp. v. Johnson & Johnson, Inc., 672 F. Supp. 135, 145 (S.D.N.Y. 1987) is also inapposite. As a factual matter, *Am. Home* is more closely akin to *POM* than the facts of this action. As in *POM,* the labeling of the product at issue in *Am. Home* (Anacin, an OTC aspirin-based pain reliever) was governed by industry-wide, uniform regulations, adopted after an extensive public notice and comment period, which required manufacturers of aspirin products to include a label warning about the risk of Reyes Syndrome. In this context, Johnson

& Johnson ("J&J") challenged the package claim "Safe, Fast Pain Relief", alleging that the word "safe" was misleading because of the risk of Reyes Syndrome. *Id.* at 145. In dismissing J&J's claim, the Court relied on the fact that the FDA had expressly found the need for national uniformity of Reyes Syndrome warnings on the labeling of aspirin products and expressly preempted all conflicting regulations, and that the Anacin label complied with the FDA's warning regulations. *Id.*

In short, in contrast to the above cases, C&D's Complaint does not allege that SPD has falsely marketed the Weeks Estimator as FDA-cleared, that SPD must obtain a new FDA clearance, that FDA erred in clearing the Product for its intended use, or that label language mandated or permitted by FDA regulations constitutes false advertising. Nor does the viability of C&D's false advertising claims depend on proving a violation of the FDCA. Here, the truth or falsity of C&D's allegations that the Weeks Estimator is incapable of measuring the duration of pregnancy and is not 93% accurate (Compl. ¶¶42-45) can be determined by this Court without reference to, or interpretation of, the FDCA or any FDA regulation.[13]

[13] The rest of the cases SPD cites also fall into one of these categories and thus, for the reasons discussed above, do not support dismissal of the Complaint. *See, e.g., Rita Med. Sys., Inc. v. Resect Medical, Inc*., 2006 U.S. Dist. LEXIS 52366 (N.D. Cal. July 17, 2006) (denying preliminary injunction where the Court could not adjudicate the claim without converting it into a de facto review of the FDA's clearance of the product for its intended use); *SmithKline Beecham v. Johnson & Johnson*, 1996 U.S. Dist. LEXIS 7257 (S.D.N.Y. 1996) (denying preliminary injunction where plaintiff's Lanham Act claim would have required the Court to enjoin defendant from advertising its heartburn product as effective for its FDA-approved use of treating heartburn symptoms when taken at least 30 minutes prior to a meal); *Cytyc Corp. v. Neuromedical Sys., Inc*., 12 F. Supp. 2d 296, 302 (S.D.N.Y. 1998) (finding statement that defendant's medical detection system was "more effective" than plaintiff's conventional pap smear system not misleading where the FDA specifically approved defendant's product, via the pre-market approval process, to be marketed as "significantly more effective" than a conventional pap smear). Finally, *PDK Labs, Inc. v. Friedlander,* 103 F.3d 1105 (2d Cir. 1997) has nothing to do with the case at bar. There, a plaintiff who had no competitive product on the market sued the defendant under the Lanham Act for selling its weight-loss product without FDA approval. The Second Circuit found that plaintiff lacked standing because he did not have a competing product in the market, and thus was not a competitor for Lanham Act standing purposes. *Id*. at 1112. The Court further noted in *dicta* that, in light of the plaintiff's lack of competitive injury, the true goal of plaintiff's pursuit of defendant for selling its product without FDA approval appeared to be to privately enforce defendant's alleged violations of the FDCA.

Courts, including those in this district, routinely allow Lanham Act claims to proceed in such situations, even where the facts or products involved are governed by FDA regulations. *See, e.g., Merck Eprova AG v. Gnosis, S.p.A.,* 2011 U.S. Dist. LEXIS 30683, at *20 (S.D.N.Y. Mar. 17, 2011) (Lanham Act claim involving FDA-regulated product not precluded where issue of falsity could be determined based on "accepted standards in the scientific and dietary supplement community," and did not depend on violation or interpretation of FDCA or FDA regulations); *Merck-Eprova AG v. ProThera, Inc.,* 2010 U.S. Dist. LEXIS 142372, at *12 (S.D.N.Y. Oct. 20, 2010) ("A plaintiff may bring a Lanham Act cause of action for affirmatively misrepresenting facts, even if the facts may be governed by FDA regulations, provided that the facts can be easily verified without requiring the truth of the fact to be determined by the FDA"); *Summit Tech. v. High-Line Med. Instruments Co.*, 933 F. Supp. 918, 933 n.7 (C.D. Cal. 1996) (Lanham Act claim involving Class II medical device permitted to proceed where the allegedly false statement "clearly misstates a fact and does not require an interpretation or application of FDA regulations"); *Mut. Pharm. Co.,* 459 F. Supp. 2d at 935 ("So long as courts are not required to perform 'authoritative interpretation and direct application of FDA regulations,' then the simple fact that a matter touches upon an area dealt with by the FDA is not a bar to proceeding with a claim under the Lanham Act").

SPD's argument that the Court cannot hear C&D's Lanham Act claim without "substituting the Court's discretion for that of the FDA" or "treading in exclusive FDA territory" (MTD Br. 12, 16) is equally meritless. As explained above, C&D is not challenging the FDA's decision to clear the Weeks Estimator to be marketed for either of its cleared intended uses: detecting the fact of pregnancy (as opposed to its duration) and estimating the number of weeks since ovulation, or any advertising statement that confines itself to communicating those

intended uses. Instead, the Complaint alleges that the challenged advertising statements convey the false message that the Product can estimate how long a woman has been pregnant. In light of the express language of the Clearance Letter, SPD cannot maintain that FDA cleared the Weeks Estimator for the intended use of estimating how long a woman has been pregnant. Quite the opposite is undeniably true: the FDA required SPD to include a statement on the Product package explaining that the Product **cannot estimate the duration of pregnancy**. Compl. Ex. A at 3. Thus, SPD's contention (MTD Br. 15) that the FDA "approved" of SPD communicating that the Product can estimate the duration of pregnancy is simply false.[14]

Moreover, SPD's brief seems to invite this Court to find that this case is only about the label of the new Weeks Estimator box that SPD currently is in the process of shipping to retailers. But as this Court knows, the Complaint alleges that the label of the Weeks Estimator box SPD sold to the public from the time of product launch through the filing of the Complaint, and that is still available in stores today, falsely communicates that the Product tells women how long they have been pregnant, as does the SPD Commercial and internet and in-store advertising. SPD admits that FDA did not see the label on the Product box discussed in the Complaint before the Product was cleared for sale, because SPD showed FDA a different package during the pre-clearance process than the one it first marketed. MTD Br. 7-8. Nor does SPD allege that FDA engaged in any pre-clearance review whatsoever of the Commercial or the other non-label advertising the Complaint alleges to be false.

[14] Nor should the Court accord any weight to SPD's suggestion (MTD Br. 13 n. 2) that the Weeks Estimator should be viewed to have undergone the review akin to the new drug application process for prescription drugs (or the pre-market approval process for Class III devices) because FDA cleared the Product with limitations, pursuant to 21 U.S.C. §360c(i)(1)(E). All § 360c(i)(1)(E) provides is that FDA "may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling," should FDA determine that such statement is necessary to prevent product misuse. *Id*. Essentially, this provision allows FDA to require some sort of additional disclosure or warning statement on the labeling if FDA thinks such disclosure is necessary to protect against consumer misuse. That is a far cry from FDA's stringent regulation of Rx drugs which, among other things, authorizes FDA to require that drug manufacturers submit TV commercials to FDA for pre-release review at least 45 days before disseminating them to the public. See 21 U.S.C. §353c.

Finally, it bears mention that to the extent the decisions SPD relies on are grounded in prudential principles of "deference" to the FDA's general expertise in regulating products governed by the FDCA, the Supreme Court's recent unanimous *Lexmark* opinion indicates that those principles are misguided. Although *Lexmark* decided who has standing to sue for false advertising under the Lanham Act, the Court addressed a question that is highly relevant not only to standing, but also to this case, namely when can a federal court dismiss on prudential grounds a case over which it has jurisdiction. The Supreme Court's short answer was: very rarely. Indeed, the *Lexmark* decision strongly cautions federal appellate and trial courts against dismissing Lanham Act cases where, as here, the plaintiff falls within the zone of interest Congress contemplated in enacting the statute, and sufficiently alleges a cause of action. *See* slip op. at 6, 9 (stating that argument that court "should decline to adjudicate [Lanham Act] claim on grounds that are 'prudential' . . . is in some tension with our recent reaffirmation of the principle that a 'federal court's obligation to hear and decide' cases within its jurisdiction 'is virtually unflagging'"; and also holding that a court "cannot limit a cause of action that Congress has created merely because 'prudence' dictates") (citations omitted).

Here, C&D has alleged (Compl. ¶¶47-49, 69) that SPD's false advertising has injured its commercial interests, causing loss of sales, profits and goodwill, and causing harm to its business reputation, and thus falls within the Lanham Act "zone of interests" articulated by the Supreme Court in *Lexmark* (slip op at 7). Moreover, as previously discussed, C&D has sufficiently alleged a cause of action under the Act. Accordingly, *Lexmark* also dictates that this Court should not dismiss the Complaint.[15]

[15] Further counseling against dismissal on either "preclusion" or "prudential" grounds is the fact that the Clearance Letter itself (like all 510k clearance letters) disclaims the preclusive effect of the determinations made during the course of the FDA's 510k review process by explicitly stating: "Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies

IV. PRIMARY JURISDICTION DOES NOT APPLY HERE

The doctrine of primary jurisdiction is intended to address the rare case where it is appropriate to defer to the expertise of a federal agency in order to serve one of two over-arching interests: "consistency and uniformity in the regulation of an area which Congress has entrusted to a federal agency; and the resolution of technical questions of facts through the agency's specialized expertise, prior to judicial consideration of the legal claims." *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig*., 2007 U.S. Dist. LEXIS 18398, at *4-5 (S.D.N.Y. Mar. 6, 2007). SPD unconvincingly argues that this case presents the rare instance in which the doctrine should be invoked, and identifies two issues that it asserts are "clearly matters for FDA decision-making": (1) whether ovulation is a legitimate reference point for estimating how long a woman has been pregnant; and (2) "whether the FDA prohibited SPD from communicating any message inconsistent with C&D's view of the science." MTD Br. 18-19. SPD asserts that the first issue is "a question of science and medicine, not of law." It contends that as to the second, FDA "is uniquely suited to resolve [it] for obvious reasons." *Id*. at 19. SPD is wrong on both counts.

SPD's first argument fails in light of the fact that it has identified no uniform regulations (labeling or otherwise) that govern the issue of whether or not ovulation is an appropriate starting point for measuring duration of pregnancy, nor is there any evidence that the FDA is currently considering promulgating any such regulations. To the contrary, FDA has **already** spoken on this precise point in **rejecting SPD's position** that the Weeks Estimator can estimate the duration of pregnancy because it can estimate when a woman last ovulated. Thus, the FDA Clearance Letter (Compl. Ex. A, at 2) explicitly states: "Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. **This test [the**

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with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies." *See* Compl. Ex. A at 3. *See also PhotoMedex, Inc*., supra, 601 F.3d at 925 n.3 ("[u]nlike premarket approval, 510(k) clearance 'does not in any way denote official approval of the device'").

Weeks Estimator] provides a different estimate." Accordingly, C&D's Lanham Act claim does not trigger the application of primary jurisdiction. *See In re Bextra and Celebrex,* 2006 WL 2374742, at *12 (N.D. Cal. Aug. 16, 2006). "Plaintiffs' false advertising claims do not implicate the primary jurisdiction doctrine. The issue is not whether Celebrex has fewer GI complications than other over-counter NSAIDs; the FDA has already determined that it does not. The issue is whether contrary to the FDA's findings, Pfizer nonetheless falsely claimed that Celebrex was superior. Courts and juries frequently decide similar false advertising claims").

Furthermore, the mere fact that a lawsuit might implicate complicated issues of medicine or science is not sufficient to invoke the primary jurisdiction doctrine. *See In re Genentech, Inc. Securities Litig.,* 1989 U.S. Dist. LEXIS 14819, at *3-4 (N.D. Cal. July 7, 1989) ("If primary jurisdiction of the FDA were appropriate whenever an action presented complex medical and pharmacological issues, the FDA would virtually have no time to regulate drugs"); *Jovel v. I-Health, Inc*., 2013 WL 5437065, at *4 n.4 (E.D.N.Y. Sept. 27, 2013) ("the primary jurisdiction doctrine 'is not designed to secure expert advice from agencies every time a court is presented with an issue conceivably within the agency's ambit'") (citing *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008)).

Contrast the facts here to those in *Gordon v. Church & Dwight Co.*, 2010 U.S. Dist. LEXIS 32777 (N.D. Cal. Apr. 2, 2010), on which SPD's motion relies (MTD Br. 18). *Gordon* represents the quintessential case where application of the doctrine may be appropriate. There, plaintiffs challenged as deceptive certain statements on the warning labels for C&D's latex condoms with nonoxynol-9 (a spermicidal lubricant), related to the condom's ability to help reduce the spread of sexually-transmitted diseases, including AIDS. C&D did not make those statements by choice; rather, an FDA regulation mandated them for all condoms. *Gordon*, 2010

U.S. Dist. LEXIS 32777, at *3. Key to the court's reasoning for dismissing the plaintiffs' claims without prejudice on primary jurisdiction grounds was that FDA was in the process of a comprehensive review of the adequacy of the warnings labels for condoms containing nonoxynol-9 lubricants, to determine if there was a need to address the same safety concerns that motivated plaintiff's lawsuit. *Id*. at *4. Thus, the *Gordon* court justified dismissal on primary jurisdiction grounds not simply because FDA had expertise in the product category, but rather because a decision by the Court would have disrupted the FDA's ongoing re-evaluation of uniform regulations concerning mandatory warnings for N9 condoms.[16] *Id*. at *5.

Finally, if the court were to dismiss C&D's claims on primary jurisdiction grounds, it would leave C&D without a remedy for SPD's unlawful and injurious behavior. *Jovel*, 2013 WL 5437065, at *8 (denying motion to dismiss in part on that ground). To the extent SPD argues that C&D's recourse is through a citizen's petition (*see* MTD Br. 18), SPD is dead wrong: the "FDA does not accept formal petitions for the FDA to take a discretionary enforcement action." U.S. Merits Br. 27. Also incorrect is SPD's argument (MTD Br. 18) that C&D first must exhaust its administrative remedies at FDA. In fact, there is no requirement that a competitor exhaust those remedies before suing under the Lanham Act. *Alpharma, Inc.,* 411 F.3d at 938

[16] *Heller v. Coca-Cola Co.,* 230 A.D.2d 768 (N.Y. App. Div. 1996) and *Bernhardt v. Pfizer, Inc.,* 2000 U.S. Dist. LEXIS 16963 (S.D.N.Y. Nov. 16, 2000) are similarly distinguishable. In *Heller,* the Court declined to hear class action plaintiffs' consumer fraud claims arising from defendants' failure to include a "use by" date on the labels of their soft drink beverages containing the artificial sweetener Aspartame, because the FDA had promulgated industry-wide regulations for Aspartame-sweetened soft drinks and thus deferral to the FDA was appropriate to ensure the continued national uniformity in the labeling of such beverages. 230 A.D.2d at 770. That is the same position the Ninth Circuit took in *POM*. Besides that the Supreme Court presently is considering reversing the Ninth Circuit on that point, *Heller*, like *POM*, is distinguishable because this case does not involve industry-wide regulations. In *Bernhardt,* the Court declined to hear plaintiff's product liability claim for injunctive relief in the form of a mandatory notice to physicians regarding defendant's prescription drug, on the ground that since the FDA was charged with regulating the safety of prescription drugs, such relief created a "substantial danger" of creating "inconsistent directions concerning a serious medical ailment and how it is best treated." 2000 U.S. Dist. LEXIS 16963, at *9. SPD's reliance on *Mut. Pharm. Co. v. Watson Pharm. Co*., 2009 WL 340117 (C.D. Cal. Oct. 19, 2009) is also misplaced. The court in *Mut. Pharm.* did not even reach the issue of whether or not primary jurisdiction was appropriate; instead, the court assumed that primary jurisdiction did not apply, and denied plaintiffs' motion for a preliminary injunction on the ground that plaintiffs failed to carry their burden of establishing a likelihood of success on the merits. *Id.* at *4-5.

(exhaustion not required because FDA lacks authority to award damages to Lanham Act plaintiff).

V. SPD'S "SUPPLEMENTAL JURISDICTION" ARGUMENT IS FRIVOLOUS

There is no issue of "supplemental jurisdiction" even in the unlikely event C&D's Lanham Act claim is dismissed. This court has diversity jurisdiction with regard to C&D's state law claims pursuant to 28 U.S.C. §1332(a). *See* Compl. ¶12.

CONCLUSION

For the foregoing reasons, SPD's motion to dismiss should be denied in its entirety.

Dated: April 11, 2014
New York, NY

By: /s/ Lawrence I. Weinstein

PROSKAUER ROSE LLP
Richard M. Goldstein
Michael T. Mervis
Lawrence I. Weinstein
Baldassare Vinti
Victoria L. Loughery
Eleven Times Square
New York, NY 10036
Tel. (212) 969-3000
Fax (212) 969-2900
rgoldstein@proskauer.com
mmervis@proskauer.com
lweinstein@proskauer.com
bvinti@proskauer.com
vloughery@proskauer.com

Attorneys for Plaintiff
Church & Dwight Co., Inc.